GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:329
ANSWERED ON:17.08.2005
CLINICAL TRIAL OF DRUGS
Singh Baba Shri K.C.

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the details of existing procedure to permit foreign companies to conduct clinical trials of drugs in the country;

(b) whether the said procedure in not as strict as in other countries, particularly USA;

(c) if so, the details thereof in the country vis-Ã -vis other countries; and

(d) the steps taken/proposed to be taken by the Government to make the procedure more stringent?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMADOSS)

(a)to(d): A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 329 FOR 17TH AUGUST, 2005

Norms for conducting clinical trial in the country including by foreign companies are prescribed under Drugs and Cosmetics Rules 122DA to 122-E and Schedule Y to the Rules. The Rules prescribe specific application form and relevant document requirements for seeking permission to conduct clinical trials. The data/documents are evaluated in consultation with subject experts.

Permission to conduct phase-I trial i.e. first time use in human being is presently not permitted for new drugs developed in foreign countries. The multicentric trials at phase-II and III stage are permitted only if similar trial has been approved by regulatory authorities of concerned foreign countries.

Schedule Y, which prescribes requirements for permission to conduct clinical trials and/or manufacture or import of new drugs for marketing in India has been extensively revised in January, 2005 to lay down safety and ethics norms, responsibilities of sponsors, investigators and Institutional Ethics Committee etc. Modalities for obtaining informed consent from clinical trial subjects, and the specific forms have also been prescribed. The Rules also provide that prior approval of Institutional Ethics Committee necessarily have to be obtained before undertaking any clinical trial in the country.

The Government has brought out detailed guidelines on Good Clinical Practices (GCP) that are required to be followed during conduct of a trial.

These norms prescribed in India, are at par with international practices including that of USA.